5. 510(k) Summary

K060832 1/2

[redacted]

MAR 13 2007

Retro-Tech

Submitter's name: Retro-Tech, LLC
Address: 7120 Nicki Ct.
Dallas, TX 75252-6125

Phone: 214-673-5465
Fax number: 972-220-0054

Name of contact person: Grace Holland
Regulatory Specialists, Inc
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411 fax: 949-552-2821

Date the summary was prepared: March 21, 2006

Name of the device: Retro-Tech Dressing
Trade or proprietary name: RTD
Common or usual name: Wound Dressing
Classification name: Wound Dressing

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

K#	Applicant	Device Name
K013462	Hydrofera, LLC	Hydrofera Blue
K022416	Coloplast Corp.	Contreet Foam Adhesive/Non-adhesive
K032742	Advanced Medical Solutions, Inc.	Silver Foam Wound Dressing

Description of the device:

The Retro-Tech Dressing is a dry medium, wound dressing. Retro-Tech Dressing is an absorbent foam. It is ideal for highly exudating wounds. It provides both antibacterial and antifungal protection. It is extremely hydrophilic.

Indications:

Retro-Tech Dressing is indicated for moderately to heavily exuding, partial to full thickness wounds, including: pressure ulcers, leg ulcers, diabetic foot ulcers, graft wounds and donor sites, skin tears, first and second degree burns, surgical wounds, lacerations and abrasions.

Summary of the technological characteristics of our device compared to the predicate device:

The predicates as listed above and RTD were compared in the following areas and found to have similar technological characteristics and to be equivalent.

- Indications For Use
- Design
- Materials
- Performance
- Sterility
- Testing Done
- In-Vitro Antibacterial Activity
- Where Used
- Anatomical Sites

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Retro-Tech, LLC
% Regulatory Specialists, Inc.
Ms. Grace Holland
7120 Nicki Court
Dallas, Texas 75262-6125

MAR 13 2007

Re: K060832
Trade/Device Name: Retro-Tech Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: Decembetr 11, 2006
Received: December 13, 2006

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K060832

Device Name: Retro-Tech Dressing

Retro-Tech Dressing is indicated for moderately to heavily exuding, partial to full thickness wounds, including:

- Pressure ulcers
- Leg ulcers
- Diabetic foot ulcers
- Graft wounds and donor sites
- Skin tears
- First and second degree burns
- Surgical wounds
- Lacerations and abrasions

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060832